

REMARKS

In a restriction requirement dated September 10, 2010, the Examiner required restriction under 35 U.S.C. § 121 between the following groups of claims:

- Group I: Claims 1-17, drawn to a plurality of conjugate molecules that vary in saccharide structure and conjugate structure;
- Group II: Claims 18-23, drawn to a plurality of saccharide molecules which differ in size and chemical structure
- Group III: Claims 24-29, and 34-35, drawn to a plurality of antibodies of different specificities and structure, and may include SEQ ID NO: 12-34;
- Group IV: Claims 30-32, and 33, drawn to a plurality of polynucleotides that encode parts or whole antibodies, expression vector and host cell; a transgenic animal or a transgenic plant that comprises the polynucleotide; or
- Group V: Claims 36-43, drawn to a plurality of processes of preparing conjugates.

Applicant elects Group I, claims 1-17, drawn to a plurality of conjugate molecules that vary in saccharide structure and conjugate structure.

In addition, the Examiner stated that the application contains claims directed to more than one species of a generic invention. The species were identified as follows:

- Group I species: Saccharide formula component A, carrier component B.
- Group II species: A single saccharide formula.
- Group III species: An antibody: i.e., one of the deposited antibodies, a chimeric antibody that contains portions of the deposited antibodies represented by SEQ ID NOs: 12-34, or fragments of

monoclonal antibodies represented by
SEQ ID NOs: 12-34.

Group IV species: The desired combination of
component A & B.

Group V species: The desired formula for use in the
claimed process of preparation.

Applicant elects the conjugate molecule comprising the pentadecasaccharide
[AB(E)CD]₃ covalently bound to tetanus toxoid.

The claims that are readable on the elected inventions are claims 1, 2, 3, 5, 7-9,
and 12-17.

Specification

The disclosure was objected to because it contains an embedded hyperlink
and/or other form of browser-executable code. Applicant was required to delete the
embedded hyperlink and/or other form of browser-executable code on page 129, line
20, paragraph [0446]. Office Action at 7. This objection has been obviated by deleting
the embedded hyperlink. Thus, the objections may be withdrawn.

Sequence Compliance/Sequence Requirements

The Examiner stated that this application fails to comply with the requirements of
37 C.F.R. §§ 1.821-1.825. Full compliance with the sequence rules was required.
Office Action at 7. According to the Examiner:

- ❖ Claim 4 recites the peptide "PADRE"; this should have a sequence identifier inserted
next the amino acid sequence. "PADRE" is not a sequence *per-se*. It is a
designation for "*proline, aspartate, arginine, glutamate*," and is an acronym which is
well known to the person skilled in the art. Its structure is disclosed in Figure 19.

Applicant courteously submits that a sequence identifier is not required for this acronym.

- ❖ Table G at page 134 describes SYA/J6 by six amino acid SEQ ID NOs 12, 35 to 39 and F22-4 by six SEQ ID NOs 12, 16, 20, 24, 28 and 32, but Table G shows 7 **peptide** sequences (see below, "PM" and "DY", being two separate peptides) for F22-4; Clarification/Correction of Table G was required. Applicant courteously acknowledges the Examiner's comment. Table G has been corrected.

Drawings

The drawings were objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the reference characters not mentioned in the description. Office Action at 8.

- ❖ Figure 1 shows the numbers 104, 109, 113 and 114 which are not described in the figure nor in the Brief Description of the Drawings on page 44 of the Specification.
- ❖ Figure 2 shows the numbers 102, 113, 118 and 119 which are not described in the figure nor in the Brief Description of the Drawings on page 44 of the Specification.
- ❖ Figure 3 shows the numbers 102 and 118 which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- ❖ Figure 4 shows the numbers 102, 105, 125 which are not described in the figure or in the Brief Description of the Drawings on page 45 of the Specification.
- ❖ Figure 8 shows the number 204 and letters a, b and c, which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- ❖ Figure 9 shows the letters a, b and c which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.

- ❖ Figure 10 shows the letters a, b and c and the numbers 208, 212, and 214 which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- ❖ Figure 11 shows the letters a, b and c and the numbers 301 and 309-313 are not described in the figure or in the Brief Description of the Drawings on page 45 of the Specification.
- ❖ Figure 12 shows the letters a-f and the numbers 309-310 are not described in the figure or in the Brief Description of the Drawings on page 45 of the Specification.
- ❖ Figure 13 shows the number 314 which is not described in the figure or in the Brief Description of the Drawings on page 45 of the Specification; the Brief Description of the Drawings describes the synthesis of pentasaccharide 313 which is not mentioned or shown in Figure 13.
- ❖ Figure 14 shows the numbers 323 and 311 which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- ❖ Figure 15 shows the numbers 311, 321, and 316 which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- ❖ Figure 16 shows the letters a, b and c and the number 346 which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- ❖ Figure 18 shows the number 405 and the letter "h" which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- ❖ Figure 19 shows the designator "S AMA-Pfp" the meaning of the term is not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.

- ❖ Figure 20 shows the letters a-h which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- ❖ Figure 21 shows the letters a-g which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- ❖ Figure 22 shows the letters a-i which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- ❖ Figure 23 shows the letters a-c which are not described in the figure nor in the Brief Description of the Drawings for this drawing on page 45 of the Specification.
- ❖ Figure 25 shows the letters a-h and numbers 608-609 which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- ❖ Figure 26 shows the letters a-f and numbers 606-608 which are not described in the figure nor in the Brief Description of the Drawings for this drawing on page 45 of the Specification.
- ❖ Figure 27 shows the letter a and numbers 606-607 and 617 which are not described in the figure nor in the Brief Description of the Drawings for this drawing on page 45 of the Specification.
- ❖ Figure 28 shows the terms "{}=BIOT" and "BIOT" which are not described in the Brief Description of the Drawings for this drawing on page 45 of the Specification; the Brief Description of the Drawings describes the synthesis of conjugates 701-713, but figure 28 only describes conjugates 701-706 and 708-713, number 707 is not a saccharide but the BIOT carrier.

- ❖ Figure 28bis is described in the Brief Description of the Drawings as showing the synthesis of conjugate number 801, but the arrows are directed in the chemical degradation of conjugate 801, to the component parts, and is therefore not the synthesis but degradation of conjugate 801; the description is not directed to what is shown in figure 28bis.
- ❖ Figure 34 shows six frames, 34A, B, C, D, E, F and G, but are not labeled as such, nor described based upon each frame shown in the figure based upon what was administered. The Brief Description of the Drawings is incomplete, and the Figure should be labeled for clarity of data presented.

Corrected drawing sheets in compliance with 37 C.F.R. §1.121(d), or amendment to the specification to add the reference characters in the description in compliance with 37 C.F.R. §1.121(b) were required. Office Action at 11. In response to these objections, the specification has been amended. Thus, the objections may be withdrawn.

General Observations

Examiner noted that the claims have a plurality of improper dependent claims. Generally, a multiple dependent claim is a dependent claim which refers back in the alternative to more than one preceding independent or dependent claim. Office Action at 11-12. The claims have been revised so that multiple dependent claims do not depend from another multiple dependent claim.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

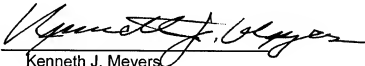
In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and formal examination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

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